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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/128,340 08/03/98 LLORIN

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RICHARD RODRICK
BECTON DICKINSON & COMPANY
1 BECTON DRIVE
MAIL CODE 089
FRANKLIN LAKES NJ 07417-1880

EXAMINER

WARE, D

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 08/30/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/128,340

Applicant(s)

Llorin

Examiner

Ware

Group Art Unit
1651



☒ Responsive to communication(s) filed on Jun 10, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1 and 3-13 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1 and 3-13 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1651

Claims 1 and 3-13 are presented for reconsideration on the merits.

The amendment filed June 10, 1999, has been received and entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1 and 3-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite for the recitation of "into said liquid" at line 3, of which the recitation lacks antecedent basis. It is suggested to change the phrase to --into said first liquid--.

Claim 5 is further rendered vague and indefinite for the recitation of "a substance or condition" because the metes and bounds of the claim can not be determined.

Claim 8 is rendered vague and indefinite for failing to recite clear and distinct process steps for the claimed method. Further the recitation of "a substance or condition" is rejected for the same reasons noted above.

Claims 9-13 are rendered vague and indefinite since it is unclear that "a second liquid" contains no beads or is at an alkaline pH since claim 10 recites "beads are in said liquid" and

Art Unit: 1651

claim 11 recites "said liquid is at an alkaline pH". There appears to be no distinction between "a first liquid" and "a second liquid"? Thus, the metes and bounds of the claims are unclear.

Claims 1 and 3-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buck et al., previously cited, in view of **newly cited** Robson et al. (note the PTO-1449 Form previously cited) and **newly cited** Robbins et al. (A).

The claims and Buck et al. are previously discussed in the Office action of March 30, 1999, see page 2.

Robson et al. teach cell lysis or disintegration of Mycobacteria using liquids having an alkaline pH, note column 6, lines 25-40. Note that the references teaches that organisms to be lysed or disintegrated can be in water, but also can be in suitable buffers having alkaline pH (i.e. Tris-HCl, pH 8.0, pH 8.8, etc.). Further, a sonification procedure on Mycobacteria is also disclosed, note column 8, lines 53-65.

Robbins et al. teach cells contained in a second liquid having an alkaline pH, see column 3, see lines 18-55, as well as sonic disintegration of the cells to obtain an alkaline extract therefrom.

The claimed subject matter is different from the disclosure of Buck et al. in that an alkaline pH is explicitly recited in the claims and further the arguments of the instantly filed response are directed to an enhancement by using such conditions.

It would have been obvious to one of skill in the art at the time of applicant's invention to provide for an alkaline pH for the liquid containing the cells as disclosed by Buck et al. and to utilize buffered solutions having an alkaline pH in place of water as disclosed by **newly cited**

Art Unit: 1651

Robson et al. for purposes of enhancing a process for disrupting cells as also disclosed by **newly cited** Robbins et al. No unexpected successful result is obtained using solutions of an alkaline pH to disrupt, lyse and/or to disintegrate cells of Mycobacteria or other cell types (i.e. yeast) for that matter. The claimed method is clearly suggested, if not taught, by the cited references.

Applicant's arguments filed June 10, 1999, have been fully considered but they are not persuasive. The argument that Buck et al. neither teaches or suggests the "placing into said liquid a vessel comprising cells in a second liquid **"at an alkaline pH"** set forth in claim 1 is not persuasive since Buck et al. teaches PCR buffer (10 mM Tris-HCl, pH 8.3) is added to the cells in a tube before sonification. The first liquid of Buck et al. is "a dish of water" next to the sonicator probe of which the tubes containing the cells and second liquid adjusted to an alkaline pH with PCR buffer are contained therein. Thus, this teaching by Buck et al. suggests a vessel comprising cells in a second liquid at an alkaline pH. However, Robson et al. and Robbins et al. clearly teach a liquid having an alkaline pH containing cells upon their sonic disintegration. Also the enhancement of using an alkaline pH is also suggested.

Therefore, the second liquid of Buck et al. is not merely residual water from previous wash steps as argued by applicant. Also the alkalization of the liquid is further suggested, if not taught, by Robbins et al. and Robson et al. The newly applied reference clearly recognizes the alkalization of a liquid and/or second liquid, the liquid containing the cells to be sonicated, to be an advantage and desirable treatment in the art for the disruption of cells. There is no unexpected

Art Unit: 1651

result obtained for mycobacterial cells. Therefore, the claimed method is deemed *prima facie* obvious over the **newly cited** art rejection.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is (703) 308-4245. The examiner can normally be reached on Mondays to Fridays from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-7939.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Deborah K. Ware

August 26, 1999


FRANCISCO PRATS
PRIMARY EXAMINER